



## **EFISC-GTP temporary monitoring for aflatoxin in maize crops and maize co-products derived thereof in feed/food materials**

### **1. Introduction**

High levels of Aflatoxin B1 in food and feed material are a real safety issue for the European food and feed sector and the last years RASFF alerts and crisis showed that a more stringent monitoring of such risk is needed in order to assure safe feed material to our customers. This situation has resulted in the need for the operators certified against the EFISC-GTP code 4.0, scope D, F and G, to follow some specific ad-hoc testing protocols, such as this new Version of our EFISC-GTP Code addendum, to better monitor such risks, in coordination with other stakeholders of maize food material and maize/maize co-products feed material supply chain.

This protocol covers **supply of maize and maize co-products for food and feed uses**.

In order to cover the potential risk for Aflatoxin occurrence in maize from any origin, the protocol has been revised.

This protocol will be applicable until further notice.

### **2. Sources of Mycotoxins**

Contamination of maize with mycotoxins can occur at two levels. The first source of contamination is infection of the crop in the field by mycotoxin producing moulds. Field and weather conditions like temperature and humidity are key factors for mould growth and mycotoxin production. However, these conditions are very difficult to control and a thorough monitoring of the crop should be applied to detect and prevent these moulds. After harvest, a second contamination with mycotoxins can take place by infection of the harvested and processed maize with storage moulds, for example by *Aspergillus* species. Infection with storage moulds occurs when storage and/or drying conditions are not optimal. Of these storage conditions, temperature and humidity are the most determining factors for mould growth and mycotoxin production. Also, the moisture content of the maize plays a crucial role. Storage conditions should be very well fine-tuned to avoid mould growth.

### **3. Existing legal requirements**

The applicable EU maximum limits for aflatoxin are:

#### **3.1. EU food limits for Aflatoxin (as per amended version of Regulation (EC) No 2023/915**

Maximum levels for aflatoxins and certain other contaminants in food are set in Regulation (EC) 2023/915 subsequent amendments	Aflatoxin B1 (µg/Kg – ppb)	Aflatoxins (B1+B2+G1+G2) (µg/Kg - ppb)
For all cereals (Raw Materials, e.g : Wheat) with the exception of Maize (Raw material)	< 2.0	< 4.0
Maize (Raw material) to be subjected to sorting or other physical treatment, before human consumption or use as an ingredient in foodstuffs	< 5.0	< 10.0
All products derived from cereals, including processed cereal products (Processed maize products)*	< 2.0	< 4.0

*\*with the exception of processed cereal-based foods and baby foods for infants and young children & Infant formulae and follow-on formulae, including infant milk and follow-on milk)*

### 3.2. For maize and maize co-products to be used as feed materials (as per amended version of Directive 2002/32/EC

Maximum levels for aflatoxins B1 and certain other contaminants in feed are set in Directive 2002/32/EC and subsequent amendments Max. content relative to feed moisture content of 12%	Aflatoxin B1 (µg/Kg - ppb)
<b>Feed materials</b>	< 20

## 4. Scope of application

### 4.1 Companies concerned

Operators certified against the EFISC-GTP code 4.0, scope D, F and G, carrying out the following activities must apply the provisions laid down in this addendum to the currently applicable version of the EFISC-GTP code 4.0, scope D, G and F:

- Processing, trading and Collection of maize originating from countries listed in Annex 2 and 3 and the maize co-products derived thereof.

### 4.2 Products concerned

The protocol described further below is applicable to:

- Maize (grains of *Zea mays* L. ssp. *mays*.) or maize co-products destined to be used as food or feed materials directly or after processing.

### 4.3. Origin

The selection of countries listed in Annex 2 was based on the origin of the maize supply as mentioned in the RASFF notifications and on the Aflatoxin data collected from certified companies from the maize crop.

### 3.4 Boundaries

This protocol is applicable to intra-EU shipments of maize and maize co-products as well as shipments of maize and maize co-products from third countries to the EU territory.

## 4.5 Derogation

This protocol does not apply to maize and/or maize co-products which have:

- already been sampled and analysed for aflatoxin B1 in compliance with the present EFISC-GTP protocol
- or from other mutually recognized or equivalent schemes (listed in Reference 2 in the Annex 3 in the EFISC-GTP Code 4.0) which have an aflatoxin protocol.

In this case, the company purchasing the maize and/or maize co-products must be informed about the analysis results of the delivered batch by means of a certificate of analysis from a laboratory which conforms to the requirements of this protocol under section 7.

The following conditions must however be fulfilled:

- The report analysis must explicitly indicate the same identification of the batch;
- The sampling method used complies with the requirements referred to in section 5;
- The laboratory complies with requirements referred to in section 7.

## 5. Risk classification

Countries of cultivation of maize included in Annex 2 (for feed) and Annex 3 (for food) are classified into 3 categories: “High”, “Medium” and “Low”. Sampling must be performed in accordance with the requirements in paragraph 7 of the current protocol.

Operator loading for first time a cargo from a new country not listed yet as high, medium or low risk, has to implement 100% monitoring<sup>1</sup> for aflatoxin B1 and once results are available, to classify the origin as “Low”, “Medium” or “High” with transmission of the information to EFISC-GTP with testing results which support the classification. The procedure to define or change the country risk categories is indicated in the Annex 1-a for feed and in the Annex 1-b for material to be used as food.

The operators (scope D) who purchase maize (food grade) in order to process it, in the event that their own data show a risk profiles of countries other than those indicated in the Annex 3, may only refer to the results of their risk assessment in line with what is indicated in paragraphs 2.4 and 4.4.3-a of the EFISC-GTP Code: feed material (co-product from food processing) must in any case be compliant with what is indicated in this protocol.<sup>2</sup>

In accordance with the precautionary principle, EFISC-GTP certified companies (code 4.0) for the scope D, G and F, must be vigilant and assess the possible aflatoxin risk when purchasing/selling maize for food and feed use and co-products, especially from countries not listed in Annex 2 and 3. In case of doubt about the country of cultivation (country of cultivation is unknown or not known with certainty), 100% monitoring applies until otherwise classified.

The latest version of the Annex 2 and 3 List of countries (valid for material to be used as feed and food), published on the EFISC-GTP website, is the valid version

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<sup>1</sup> Batch by batch sampling. Batch max size according to the tables in paragraph 6.1 and 6.2 of this protocol

<sup>2</sup> Maize by-products have to be analyzed by the EFISC-GTP industry according to the internal monitoring plant. These results need to be reported to the customer on his request. Alternatively, the EFISC-GTP industry can inform the client about the results of analysis on the incoming maize and the concentration factors during the process established by the industry. This information must demonstrate that the maize by-product does not exceed the limits indicated in this module or eventual other limits indicated in the agreement between the EFISC-GTP industry and the client.

## 6. Monitoring, sampling and analysis

If EFISC-GTP companies (code 4.0) certified for the scope D, G and F, have information that a certain country has a lower or a higher risk than the one indicated in the table in Annex 2, he must inform EFISC-GTP management supporting its statement by relevant data and any additional information available. It is the responsibility of the operator to apply the relevant addition controls that he might deem necessary.

### 6.1 Monitoring frequency

Based on the defined risk level, the operator shall respect the following monitoring frequency:

#### Monitoring frequency

<b>Risk estimate to be established</b>	100% monitoring Send data to EFISC-GTP until a country is categorized
<b>High</b>	100% monitoring
<b>Medium</b>	100% monitoring
<b>Low</b>	Based on the operators risk assessment as described in the <a href="#">Sector reference document on the collection, storage, trade and transport of safe feed/food ingredients</a> or <a href="#">Sector reference document on the manufacturing of safe feed materials from starch processing and paragraph 4.4.3-a of the Code EFISC-GTP</a> .

### 6.2 When collecting maize in warehouses located in the countries “at risk”

If collection is done on the basis of receipt of truck, batches and wagons, all incoming trucks or trains should be sampled according to point 6 in the current protocol based on applicable GAFTA 124 contract rules or in accordance with [Commission Regulation \(EU\) 691/2013](#) amending [Regulation \(EC\) 152/2009](#).

- If the test results are above the EU maximum limits applicable for the foreseen feed use of the products, the cargo cannot be used in food or feed. The suppliers and the authorities shall be duly and quickly informed as per applicable local regulations or rules. If the results are confirmed, the relevant authorities and the EFISC-GTP management should be informed.

### 6.3. When purchasing maize and/or maize co-products on an in or ex-warehouse basis

Each batch/cell of the cargo in the warehouse will be sampled. The batch tested cannot be physically delivered to EU locations of customers as long as the analysis results<sup>3</sup> are unknown or if results are not compliant with EU maximum limits for aflatoxins in feed materials<sup>4</sup>. The stored batches will remain in quarantine pending the results. If the whole batch in the warehouse is not accessible for sampling, a sampling plan shall be made and documented, that covers the accessible part of the batch. The part of the batch that has not yet been sampled and tested, should be monitored once it's possible and safe to get access. See Annex 4 for sampling rules.

<sup>3</sup> Analyses done before loading will be accepted as long as sampling/analyses has been done no more than three months prior to the loading operation

<sup>4</sup> In cases where maize is stored longer than 3 months in a silo and is not accessible for sampling before delivery to the customer, sampling may be carried out during loading. The results must be available before unloading at the customer or at least before the next processing step or feeding (if there is a written agreement between the seller and the customer).

- If the results are compliant with EU maximum limits, the tested batches can be loaded into sea going vessels, inland waterway transports or trucks or railways without further testing, as long as all measures are taken to preserve the identity of the concerned batches. These analyses done before loading will be accepted as long as sampling/analyses have been done no more than three months prior to the delivery<sup>5</sup>.
- If the results are above EU maximum limits for the intended use, the suppliers and the authorities shall be duly and quickly informed as per applicable local regulations or rules. If the results are confirmed, the relevant authorities and the EFISC-GTP management should be informed.
- In case of stored batches and reanalysis after three months, the highest measured Aflatoxin B1 value (from all sampling moments) is leading since it is not obvious that Aflatoxin B1 content could decrease over time. All analysis results applicable for the batch (also the expired ones) must accompany the batch.

Testing results are to be supplied to the concerned customers.

The remainder of each aggregated samples should be also sealed, duly labelled and kept in adequate storage conditions as indicated in the EFISC-GTP code 4.0. Finally, this requirement is not applicable to samples taken during collection if made on a truck per truck or wagon per wagon basis. Samples must be stored at a temperature that will not alter their composition and in such conditions that the samples are not adversely affected by light.

#### 6.4 When buying F.O.B. or C.I.F.: Loading (or unloading) of a seagoing vessel or of an Inland waterway transport

The batches tested should not be physically delivered to EU locations of customers as long as the analysis results are unknown or if results are not compliant with EU maximum limits for aflatoxins in feed materials.

For cargoes coming from High and Medium risk countries outside EU/in EU, the discharging or transshipment is allowed, in segregated spaces, as long as the user can prove that it has not been used till the results are known.

The analysis results for the other categories will be available upon request.

- If the results are compliant with EU maximum limits, the tested batches can be unloaded/released/marketed/used. Additional local testing requirements must be taken into account, where appropriate.

If the results are above EU maximum limits for the intended use, and if the results of the testing at loading are available prior to the arrival of the transport at destination, then a full re-testing of the cargo should be done, using the same methodology /procedure previously described, in order to ascertain newly the exact safety status of the cargo. If the results are confirmed, the relevant authorities and the EFISC-GTP management should be informed if cargo has been shipped in EU. Available testing results are to be supplied to the concerned customers, on request.

The remainder of each aggregated samples should be also sealed, duly labelled and kept in adequate storage conditions as indicated in the EFISC-GTP Code 4.0. Samples must be stored at a temperature that will not alter their composition and in such conditions that the samples are not adversely affected by light.

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<sup>5</sup> For low-risk countries, this requirement is based on the operator's risk assessment.

## 7. Table overview of sampling requirements

### 7.1 As per GAFTA 124 contractual rules (food and feed)

	Trucks	Trains	Barges/coasters	Vessels
<b>Sampling point</b>	Representative sample should be taken at loading or unloading of the transport means <sup>6</sup>			
<b>Batchmax size</b>	1000 mt	1 final sample per train	1 final sample per barge	1 final sample per hold
<b>Minimum number of incremental samples</b>	<p>Minimum 5 incremental samples per truck when weight of truck &lt;15 mt.</p> <p>Minimum 8 incremental samples per truck when truck weight &gt;15 mt.</p> <p>A minimum of 40 incremental samples should be taken per parcel of various trucks.</p>	Minimum 20 incremental samples every 500 metric tons sub lot, ensuring a minimum of 40 incremental samples in case the parcel is below 1000 mt		
<b>Weight of each incremental sample</b>	Max 1 kg			
<b>Minimum bulk aggregate sample per lot</b>	Min 20 kg sample per sub-lot of 500 mt (batch size 0 to 5000 mt) or min 30 kg per sub-lot of 1000 mt (batch size 5001 to 10 000 mt)			
<b>Final sample</b>	<p>Min 1 sample of min 4 kg to be fully grinded by the laboratory and well homogenized before extraction of the final sample (at least 500 grams).</p> <p><b>(For contractual samples required for analysis tests and arbitration purpose as of GAFTA Sampling Rules No. 124: min. 10kg)</b></p>			
<b>Sample for the analysis</b>	The sample for the analysis is prepared from the final sample. The remains of the final sample have to be retained for re-analysis			
<b>Analyses</b>	To be done by laboratory accredited according ISO 17025			
<b>Sampling<sup>7</sup></b>	To be done by an inspection company accredited according to ISO 17020 or according an ISO 9001 certified + GAFTA approved body			

<sup>6</sup>Analyses done before loading will be accepted as long as sampling/analyses has been done no more than three months prior to the loading operation

<sup>6</sup> The use of an accredited sampler for road transport is not required if a batch of maize has already been analyzed (original batch). The batch is not required to be analyzed again if the following requirements are met in a demonstrable manner:

- The analysis certificate shall explicitly include the same identification of the batch;
- The sampling method, batch size and laboratory satisfy the requirements indicated in the protocol;
- The analysis has been performed within the time limit mentioned in this protocol.

Moreover, for maize transported by truck in low and medium risk countries, sampling can be performed by a qualified person, who is trained and experienced in the sampling of feed and can take the appropriate care when sampling. This qualification is to be documented by records of education, experience and training of the sampler.

7.2 As per [Commission Regulation 2024/771](#) amending [Commission Regulation \(EC\) 152/2009](#) (for feed)

	Trucks	Trains	Barges/coasters	Vessels
<b>Sampling point</b>	Representative sample should be taken at loading or unloading of the transport means <sup>8</sup>			
<b>Batchmax size</b>	1000 mt	1 final sample per train	1 final samples per barge	1final samples per hold
<b>Minimum number of incremental samples</b>	<p>Minimum 5 incremental samples per truck when weight of truck &lt;15 mt.</p> <p>Minimum 8 incremental samples per truck when truck weight &gt;15 mt.</p> <p>A minimum of 40 incremental samples should be taken per parcel of various trucks.</p>			
<b>Weight of each incremental sample</b>	Max 1 kg			
<b>Minimum bulk aggregate sample per lot</b>	Min 4 kg			
<b>Final sample to be analysed</b>	<p>Aggregate sample can be representatively reduced to at least 4kg to be fully grinded by the laboratory and well homogenized before extraction of the sample for the analysis (at least 500 grams).</p> <p><b>(Recommended volume is 10 kg which would lead to less false negatives and positives)</b></p>			
<b>Sample for the analysis</b>	The sample for the analysis is prepared from the final sample. The remains of the final sample have to be retained for re-analysis			
<b>Analyses</b>	To be done by laboratory accredited according ISO 17025			
<b>Sampling<sup>9</sup></b>	To be done by an inspection company accredited according to ISO 17020 or according an ISO 9001 certified + GAFTA approved body			

<sup>8</sup>Analyses done before loading will be accepted as long as sampling/analyses has been done no more than **three months** prior to the loading operation

<sup>9</sup> The use of an accredited sampler for road transport is not required if a batch of maize has already been analysed (original batch). The batch is not required to be analysed again if the following requirements are met in a demonstrable manner:

- The analysis certificate shall explicitly include the same identification of the batch;
- The sampling method, batch size and laboratory satisfy the requirements indicated in the protocol;
- The analysis has been performed within the time limit mentioned in this protocol.

Moreover, for maize transported by truck in low and medium risk countries, sampling can be performed by a qualified person, who is trained and experienced in the sampling of feed and can take the appropriate care when sampling. This qualification is to be documented by records of education, experience and training of the sampler.

### 7.3 As per [Commission Regulation \(EU\) 401/2006 \(for food\)](#)

This method of sampling is for official control of the levels of mycotoxins in foodstuffs. On condition that **the subplot can be separated physically**, each lot shall be subdivided into sublots according to the following table 1. Considering that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the subplot may exceed the mentioned weight by a maximum of 20 %. In case the lot is not or cannot be physically separated into sublots, a minimum of 100 incremental samples is taken from the lot.

- Each subplot shall be sampled separately.
- Number of incremental samples: 100.
- The weight of the incremental sample shall be about 100 grams,
- Weight of the aggregate sample = 10 kg.

#### General survey of the method of sampling for cereals and cereal products

**Table 1. Subdivision of lots into sublots depending on product and lot weight**

Commodity	Lot weight (tons)	Weight or number of sublots	Number of incremental samples	Aggregate sample weight (kg)
Cereals and cereal products	≥ 1500	500 tons	100	10
	> 300 and < 1500	3 sublots	100	10
	≥ 50 and ≤ 300	100 tons	100	10
	< 50		3 – 100 (X)	1-10

(X) depending on the lot weight (tons). See next table

**Table 2. Number of incremental samples to be taken depending on the weight of the lot of cereals and cereal products**

Lot weight (tons)	Number of incremental samples	Aggregate sample weight (kg)
≤ 0,05	3	1
>0,05 - ≤ 0,5	5	1
>0,5 - ≤ 1	10	1
>1 - ≤ 3	20	2
>3 - ≤ 10	40	4
>10 - ≤ 20	60	6
>20 - ≤ 50	100	10

If it is not possible to carry out the method of sampling set out in this point because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented. An alternative method of



sampling may also be applied in cases where it is practically impossible to apply the above mentioned method of sampling. This is e.g. the case where large lots of cereals are stored in warehouses or where cereals are stored in silos.

*The application of sampling rules in accordance with EN ISO 24333:2009 or GAFTA Sampling Rules 124, applied by food business operators to ensure compliance with provisions in legislation is equivalent to the sampling rules set out in Table 1. For the sampling of lots for Fusarium-toxins, the application of sampling rules in accordance with EN ISO 24333:2009 or GAFTA Sampling Rules 124, applied by food business operators to ensure compliance with provisions in legislation is equivalent to the sampling rules set out in part B.*

**In the case of large sampled portions (sampled portions > 500 tons), the number of incremental samples to be taken = 100 incremental samples +  $\sqrt{V}$  tons**

The weight of the incremental sample shall be about 100 grams

## 8. Analysis requirements

Samples must be analysed on aflatoxin B1 level. This analysis must be carried out by a laboratory which is accredited according to ISO17025 for the aflatoxin analysis in the products covered by this protocol.

## 9. Reporting analysis results

EFISC-GTP certified companies (code 4.0, scope D, G and F) must report every month to EFISC-GTP ([fulvio.pernice@efisc-gtp.eu](mailto:fulvio.pernice@efisc-gtp.eu)) the analysis results in line with the EFISC-GTP monitoring template : in order to avoid duplication of data, **this obligation does not apply to Starch Europe industries (or industries processing maize) that have sourced maize material from traders certified against the EFISC-GTP code (scope G and/or F) or certified against schemes mutually recognized as indicated in the Annex 3 of the EFISC-GTP Code.** Companies are requested to declare in the communication whether the material will be used as feed or food. Collected data will be handled with confidentiality. They will be compiled into an internal monitoring database for the products covered by this protocol as per rules stated in paragraph 4 of this addendum. Collected data will only be shared anonymously and in the framework of the mutual recognition between scheme owners. If the results show level of aflatoxin above the EU maximum limits, requirements laid down in the currently applicable EFISC-GTP Code 4.0, must be complied with.

## 10. Definitions

**Lot (or Batch):** an identified quantity of a product, determined to have common characteristics, such as origin, variety, type of packing, packer, consignor or labelling, and in case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together (Commission Regulation (EC) No 767/2009 as amended). Based on the above statement, the batch is to be defined by the operator based on the physical hold (ship compartment) or a combination of holds (train, truck).

**Sampled portion:** a lot or an identified part of the lot and/or of the sub-lot.

**Sealed sample:** a sample sealed in such a manner as to prevent any access to the sample without breaking or removing the seal. The seal's mark should be clearly identifiable and clearly visible. Alternatively, the sample can be put in a recipient which can be closed in such a manner that it cannot be opened without irreversibly damaging the recipient, avoiding the re-use of the recipient.

**Identification of the sample:** the sample has to be indelibly marked and must be identified in such a way that there is an unambiguous link to the sampling report.

**Incremental sample:** a quantity taken from one point in the sampled portion.

**Aggregate sample:** an aggregate of incremental samples taken from the same sampled portion. From each aggregate sample at least two (or three) final samples are taken: 1 for control (enforcement), one for trade (defence) and eventually one for reference

**Reduced sample:** a part of the aggregate sample, obtained from the latter by a process of representative reduction.

**Final sample:** a part of the reduced sample or of the homogenised aggregate sample.

**Laboratory sample:** a sample intended for the laboratory (as received by the laboratory) and can be the final, reduced or aggregate sample.

**Test aliquot:** a measured portion of the final sample taken for analysis.

**Annex 1 a - Internal procedures to define or change risk categories (for feed material)**

EFISC-GTP, will share anonymously results with the other mutually recognized schemes in order to evaluate the country risk classification (on a monthly basis) based on the criteria as given in the table below:

Risk level by region	% of analyses per country	Analysis results (x)
High	> 1%	> 20ppb; OR
	> 10%	10ppb < x ≤ 20ppb
Medium	Any scenario not listed as High or Low	
Low	< 1%	5ppb < x ≤ 10ppb; AND
	> 90%	< 2ppb; AND
	Remaining (max 9%)	≤ 5ppb

- a. For upgrading a country of cultivation to a higher risk level, the number of samples to be tested is at least 1.
- b. For downgrading a country of cultivation to a lower risk level, the number of samples to be tested is at least 50 (new results).
- c. In addition to a. and b., other relevant criteria and resources can be used for reclassifying a country of origin

**Annex 1 b - Internal procedures to define or change risk categories (for food material)**

EFISC-GTP, will share anonymously results with the other mutually recognized schemes in order to evaluate the country risk classification (on a monthly basis) based on the criteria as given in the table below:

Risk level by region	% of analyses per country	Analysis results (x)
High	> 1%	> 5 ppb; OR
	> 10%	2 ppb < x ≤ 5 ppb
Medium	Any scenario not listed as High or Low	
Low	< 1%	2 ppb < x ≤ 4 ppb; AND
	Min 99 %	< 2ppb

- a. For upgrading a country of cultivation to a higher risk level, the number of samples to be tested is at least 1.
- b. For downgrading a country of cultivation to a lower risk level, the number of samples to be tested is at least 50 (new results).
- c. In addition to a. and b., other relevant criteria and resources can be used for reclassifying a country of origin

**Annex 2 – Table of countries of origin (for feed material)**

HIGH RISK	MEDIUM RISK	LOW RISK
<p>Hungary</p> <p>Serbia</p>	<p>All other countries not listed as low or high level</p>	<p>Austria</p> <p>Belgium</p> <p>Czech Republic</p> <p>Denmark</p> <p>Estonia</p> <p>Finland</p> <p>France</p> <p>Germany</p> <p>Iceland</p> <p>Ireland</p> <p>Latvia</p> <p>Lithuania</p> <p>Luxembourg</p> <p>Netherlands</p> <p>Norway</p> <p>Poland</p> <p>Sweden</p> <p>UK</p>

**Annex 3 – Table of countries of origin (for food material)**

HIGH RISK	MEDIUM RISK	LOW RISK